DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/2009 has been entered.

Status of Action

Receipt of Amendments/Remarks filed on 11/30/2009 and 12/03/2009 are acknowledged. Claims 2-4 and 6-12 are pending in this application. Claims 1, 5 and 13-16 have been cancelled and claims 2-4 and 6-12 have been amended.

Receipt of Declarations of 37 C.F.R. 1.132 filed on 11/30/2009 and 12/03/2009 are acknowledged. They have been considered and placed in the file.

Status of Claims

Accordingly, claims **2-4 and 6-12** are presented for examination on the merits for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejection(s) is/are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Response to Arguments

Applicants' arguments filed on 11/30/2009 with respect to the previously rejection, under 35 U.S.C. 112, second paragraph, as being indefinite have been fully considered and are mooted due to the amendments of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

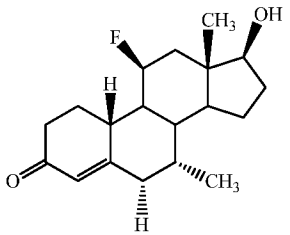
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-4 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohlmann et al. (WO 02/059139) in view of Krattenmacher et al. (Canadian Patent No. 2208605).

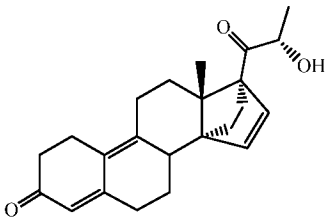
Applicants Claim

Applicants claim a composition comprising: (**i**) a compound of 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one (as structure **A** shown below) and (**ii**) a compound of (21S)-21-hydroxy-21-methyl-(4, 17-ethano-19-norpregna-4, 9, 15-trien-3, 20-dion (as structure **B** shown below), wherein the composition further comprises a pharmaceutically compatible vehicle and/or adjuvant:



A

and



B

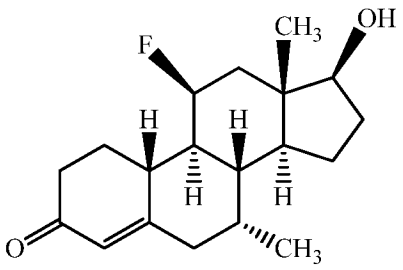
Applicants also claim a male contraceptive combination, which comprises: (**i**) a compound of 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one (as structure **A** shown above) and (**ii**) a compound of (21S)-21-hydroxy-21-methyl-(4, 17-ethano-19-norpregna-4, 9, 15-trien-3, 20-dion (as structure **B** shown above).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Bohlmann et al. teach a composition comprising an androgenic 11β-halogen steroid, which is used for the preparation of a pharmaceutical composition for male birth control therapy (also known as male contraceptive) (see page 1: lines 1-11 and all structures in pages 5-11).

Bohlmann et al. teach that the compound: **11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one** is an 11β-halogen androgen steroid, which has a chemical structure represented as follows (see page 14: lines 15-16 and Figure 1: compound I):



Bohlmann et al. also teach that the androgenic 11β-halogen steroid: 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one can be formulated with at least one pharmaceutical compatible vehicle and adjuvants, i.e. surfactants, lubricants, fillers (page 11: lines 19-21 and page 21: lines 17-24), and can be administered orally, parenterally or percutaneously (page 20: lines 16-19). It should be noted that percutaneous is commonly referred as transdermal.

Bohlmann et al. further teach that the androgenic 11β-halogen steroid, as set forth above, can be implanted in the tissues or made into various forms, such as the form that is suitable for use t release the androgenic 11β-halogen steroid to the body gradually (page 20, lines 18-19 and page 21, line 3-9).

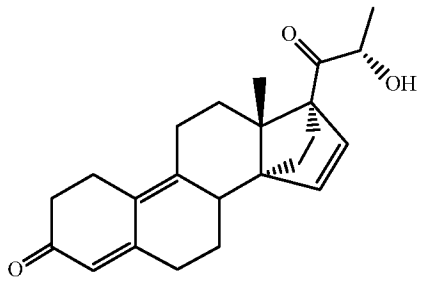
Bohlmann et al. further teach that the androgenic 11β-halogen steroid can be used in combination with a progestogen to control male fertility (page 2, lines 5-7 and page 13, lines 3-16).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Bohlmann et al. suggest the androgenic 11β-halogen steroid can be used in combination with a progestogen for controlling male fertility; however, Bohlmann et al. do not exemplify the progestogen, as instantly claimed. The deficiency is cured by the teaching of Krattenmacher et al.

Krattenmacher et al. teach a 14, 17-C_2-bridged steroid of formula (I) that has a good gestagenic action. More specifically, Krattenmacher et al. teach that the gestagen of formula (I) is (21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4, 9, 15-triene-3, 20-dione (see page 7, lines 22-23), which has a chemical structure represented as follows:



Krattenmacher et al. also teach that the gestagenic compound can be used alone or in combination with other steroids in preparations for contraception purposes (page 9: lines 19-21).

Krattenmacher et al. further teach that the pharmaceutical vehicles and diluents can be combined with the gestagenic compound set forth above and can be made into formulations for the administration by orally, or through a transdermal system, or transdermally (page 11: lines 8-14 and page 12: lines 1-3).

Finding of prima facie obviousness Rational and Motivation
(MPEP 2142-2143)

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teaching of Bohlmann et al. with Krattenmacher et al. to arrive at the instant invention.

One of ordinary skill would have been motivated to do this because the androgenic steroid: 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one is known in the relevant art for use in male birth control therapy. It is also known that the androgenic steroid 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one can combine with a progestogen (or commonly referred as gestagen), such as the gestagen: (21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4, 9, 15-triene-3, 20-dione, as taught by Krattenmacher et al., for use in the preparation of contraception medicaments.

Therefore, the Examiner can only conclude that it would have been obvious for one of ordinary skill in the art to utilize the androgenic steroid 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one in combination with the gestagenic steroid (21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4, 9, 15-triene-3, 20-dione to produce a pharmaceutical composition or product that is effective for reducing spermatogenesis and for controlling fertility, as suggested by the prior art.

From the teaching of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants' arguments filed on 11/30/2009 have been fully considered but they are not persuasive.

Applicants argue that the results attached in the declaration demonstrating significant unexpected advantages of the claimed invention over the closest prior art (see Remarks filed on 11/30/2009, page 6).

The argument is not persuasive because the prior art, namely Bohlmann et al. and Krattenmacher et al., appear to teach the identical androgenic and gestagenic steroids, as those claimed in the instant invention.

More specifically, the primary prior art **Bohlmann et al.** teach a composition comprising an androgenic 11β-halogen steroid, which is used for the preparation of a pharmaceutical composition for male birth control therapy. Bohlmann et al. also specifically teach one of the suitable 11β-halogen androgen is **11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one**, which appears to be the same steroid compound (see compound A set forth above) as instantly claimed. Bohlmann et al. further suggest that the androgenic 11β-halogen steroid can be used in combination with a progestogen to control male fertility.

The secondary prior art, namely **Krattenmacher et al.**, teach a pharmaceutical composition comprising a 14, 17-C_2-bridged steroid of formula (I), i.e. **(21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4, 9, 15-triene-3, 20-dione** set forth above, that has a good gestagenic action. Krattenmacher et al. also teach that such gestagenic compound is suitably used alone or in combination with other steroids in preparations for contraception purposes. It should be noted that (21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4, 9,

15-triene-3, 20-dione appears to be the same steroid as the claimed second agent (see compound B).

In summary, the primary reference teaches the first steroid (compound A) in combination with the generic class of progestagen (which also refers as gestagen) and the secondary reference tecahes the preferred species (compound B) of the class of progestagen in combination with the class of first agent, and both references suggest their utility and suitability for contraceptive purposes, as the instant invention. Therefore, it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven,* 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

In addition, Applicants also argue that the recitation of the terms "such that" and "suitable for" in the claims are not optional language and are positive recited without any room for them being optional with respect to the form of the formulation (see Remarks filed on 11/30/2009: page 7).

The argument is not persuasive because the term "suitable for" means capable of or being capable for a specific purpose, but, still, it does not positively recite the formulation is an implantable form or requires the formualtion to be an implantable form. Thus this is not considered a patentable (or necessary) limitation of the claim.

Response to Declaration

The Declarations of 37 C.F.R. 1.132 filed on 11/30/2009 and 12/03/2009 have been fully considered but they are not persuasive because the figures and results are written in German, and the examiner is unable to comprehend the results in the Declaration side-by-side with the closest prior art.

In addition, Applicants conclude that the data and results disclosed in the Declaration provide evidence of synergism for the combination of the claimed compounds, as opposed to what was known in the art (see Declaration, page 4, No. 3).

The conclusion is not persuasive because the features upon which Applicants rely upon (e.g. the synergism effect) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claim(s). See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, the Declaration is not commensurate with the scope of the claimed invention.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. C./

Examiner, Art Unit 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616